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No. 99-1223

In the Supreme Court of the United States

JOHN HANLON AND RUTH ANN HANLON, ETC., ET AL.,
PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Court of Federal Claims and Court of Appeals for the Federal Circuit correctly held that a special master considering two petitions filed under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, did not abuse her discretion in reconsidering, prior to the entry of final judgment, her initial entitlement ruling in light of new and dispositive medical evidence regarding the true cause of claimants' medical condition.

LIST OF PARTIES

Petitioners' list of parties erroneously includes twelve petitioners in other cases involving petitions for compensation filed under the Vaccine Act. Although all the cases involve a claimant who suffers from the genetic disease tuberous sclerosis, each of those twelve cases is pending at different stages of proceedings before the Court of Federal Claims, Office of Special Masters. Each case is being, or has been, assessed by the special master based on the medical and clinical course of the party's particular condition. With the exception of Hanlon and Plavin, none of the other petitioners listed is a party "to the proceeding in the court whose judgment is sought to be reviewed," the Court of Appeals for the Federal Circuit. Sup. Ct. R. 14(1)(b).

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OPINIONS BELOW

The opinion and order of the court of appeals in *Hanlon* v. *HHS* (Pet. App. 143a-150a) is reported at 191 F.3d 1344. The companion order of the court of appeals in *Plavin* v. *HHS* (Pet. App. 151a) is reported at 184 F.3d 1380.

JURISDICTION

Two separate judgments of the court of appeals in *Hanlon* v. *HHS* and *Plavin* v. *HHS* were entered on September 8, 1999. A combined petition for rehearing and suggestion for rehearing en banc was denied on October 20, 1999 (Pet. App. 152a-153a). A single peti-

tion for a writ of certiorari was filed on behalf of the claimants in both cases on January 18, 2000. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.*, as amended, established a federal compensation scheme for individuals alleging injury by certain vaccines. 42 U.S.C. 300aa-10 *et seq.* The Act created an Office of Special Masters as an adjunct to the Court of Federal Claims; the exclusive mission of that Office is to adjudicate Vaccine Act petitions. 42 U.S.C. 300aa-12(c); H.R. Rep. No. 908, 99th Cong., 2d Sess., Pt. 1, at 16 (1986); see also *Shalala* v. *Whitecotton*, 514 U.S. 268, 269-270 (1995). Thus, under the provisions of the statutory scheme, "Congress assigned to a group of specialists, the special masters * * * the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims." *Hodges* v. *HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993).

Designed as an alternative to traditional tort litigation, the Vaccine Act removes many of the more difficult elements of proof plaintiffs faced in civil judicial proceedings. For example, petitioners do not have to prove either that the vaccine manufacturer or administrator was negligent or that the vaccine was defective. See *O'Connell* v. *Shalala*, 79 F.3d 170, 172 (1st Cir. 1996). Additionally, with respect to proof of causation, the Act provides a burden-shifting device known as the Vaccine Injury Table. 42 U.S.C. 300aa-14(a). In "on-Table" cases, petitioners do not have to prove that the vaccine itself was responsible for the injuries alleged as

part of their case in chief. Rather, where petitioners establish that the onset or significant aggravation of certain predicate injuries is temporally associated with immunization, the Table gives rise to a prima facie presumption that the vaccine caused those injuries. See *Shalala* v. *Whitecotton*, 514 U.S. at 270. The presumption, however, is rebuttable. Thus, under the statute, no petitioner is entitled to compensation if the Table event is attributable to factors unrelated to the vaccine. 42 U.S.C. 300aa-13(a)(1)(B). The Table event in each of the instant cases consisted of a brief seizure unaccompanied by any other symptoms.

2. The present matter involves petitions for compensation under the Vaccine Act filed by the parents of Michael Hanlon and Rachel Plavin, who both suffer from the genetic disease Tuberous Sclerosis (TS).[1] TS is a known genetic disorder that can cause a variety of problems in a wide range of organ systems and tissues. Pet. App. 18a-19a. Common among these manifestations, and most important for cases brought under the Vaccine Act, TS causes cortical lesions, or tubers, to form in the brain during early fetal development. *Id.* at 19a, 72a. These tubers cause a variety of neurologic symptoms, including seizures and mental retardation. *Ibid.* Tubers lead to seizures in the majority of TS patients, and the majority of those with seizure disorders are mentally retarded. *Id.* at 72a. Medical literature on TS consistently reports that the extent of brain disruption caused by tubers is directly related to the severity of a child's outcome. *Id.* at 19a, 27a-36a, 72a.

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[1] Michael Hanlon was born on March 30, 1978, Pet. App. 2a; Rachel Plavin was born on June 8, 1989, *id.* at 9a.

Michael Hanlon was born with at least ten tubers in his brain. Pet. App. 24a, 60a. Rachel Plavin was born with at least 43 tubers in her brain. *Id.* at 24a & n.6, 64a. As with many children who suffer genetic disorders and virtually all children who suffer from TS, the symptoms caused by the children's disease were not immediately apparent at birth. On June 1, 1978, at two months of age, Michael received his first Diphtheria, Pertussis and Tetanus (DPT) vaccination; he experienced his first seizure the following day. *Id.* at 7a. On September 15, 1989, at the age of three and one-half months, Rachel received her second in a series of DPT immunizations, and she experienced her first seizure later that day. *Id.* at 9a. Aside from the onset of seizures typical of TS, neither Michael nor Rachel suffered any symptoms of vaccine reaction such as fever, anorexia, insomnia, excessive sleeping or coma, shock, or any other changes that might suggest something other than their genetic disease was responsible for seizure onset. *Id.* at 71a, 73a, 74a.

3. Petitioners filed petitions for compensation under the National Vaccine Injury Compensation Program alleging that each child suffered "significant aggravation of pre-existing tuberous sclerosis (TS)" in the form of a residual seizure disorder "within the Table time limits of the Act." Pet. App. 2a, 9a. In each case, the special master initially ruled for petitioners. Based on the medical evidence available at the time, the special master concluded that, when a child with TS has his first seizure within three days of receiving a DPT vaccine, he is entitled to compensation under the Vaccine Act regardless of the nature of the seizure, the existence of any other symptoms, or the subsequent clinical course. *Id.* at 7a, 12a. These decisions were issued in 1994, *id.* at 1a, 8a, after which the special

master initiated the damages phase of proceedings. In 1995, while the cases were still pending before the special master, the Secretary filed motions for reconsideration in each case, based on additional evidence previously unavailable, including peer-reviewed published medical literature. *Id.* at 16a, 84a. Specifically, the Secretary asked the special master to consider testimony, in light of this new evidence, on the question whether each child's seizures and mental retardation were caused by TS alone. *Id.* at 84a.

After reviewing the proffered evidence and considering extensive briefs filed in opposition to reconsideration, the special master granted the motions and undertook the "colossal task," Pet. App. 90a, of convening omnibus proceedings to consider the common issues in these and numerous other cases arising out of the complex medical and scientific questions related to TS. *Id.* at 14a-18a. Those proceedings included discovery, six days of expert trial testimony involving nine expert witnesses, more than 2000 pages of evidentiary transcripts, and the consideration of numerous briefs, as well as over 200 medical articles, reports, and other exhibits. The special master also heard evidence in the particular cases of Michael Hanlon and Rachel Plavin, so as to have specific details to which to apply the general defenses set forth by the Secretary. *Id.* at 24a.

3. Ultimately, the special master found their underlying genetic disease, TS, to be the medical cause of Michael Hanlon's and Rachel Plavin's seizures and mental retardation. The special master found further that their seizure onset and subsequent medical course were unrelated to the DPT immunizations. Pet. App. 73a-74a. As the special master explained, "[t]he effect of numerous tubers, as well as their location and size, is a given. Not one witness disputes their importance."

Id. at 72a. The special master examined both Michael Hanlon's and Rachel Plavin's medical course to determine whether either had any signs or symptoms that might indicate that something other than the genetic disease was responsible for their condition, and concluded that neither had any such symptoms. *Id.* at 72a-74a. To the extent petitioners' experts offered contrary opinions regarding the cause of each child's disorder, the special master found that, "[b]y espousing minority views," the testimony of those experts, "though admissible under the broad directives of the Vaccine Program (which does not adhere to the Federal Rules of Civil Procedure)," was not as credible as that of the experts who adhered to "mainstream" methodology. *Id.* at 60a n.41. In light of the voluminous record, the special master concluded that, when no signs of a typical vaccine reaction are seen, it would be unreasonable, arbitrary and capricious "to hold that TS, a disease known to produce seizures, and consequent mental retardation, autism, and developmental delay, is not the cause and that respondent has failed to rebut the presumption that DPT is the cause." *Id.* at 69a. Because the Secretary had proven by a "logical sequence of cause and effect" that TS, rather than immunization, was the cause of Michael's and Rachel's seizures and retardation, petitioners were not entitled to compensation under the Vaccine Act. *Id.* at 72a. The special master then issued orders vacating her initial entitlement ruling and dismissing both cases. *Id.* at 75a-78a.

4. Petitioners moved for review of the special master's decision in the Court of Federal Claims; the cases were heard by two different judges. In *Hanlon*, the court affirmed both the special master's decision to reconsider her interim entitlement ruling in light of

new evidence, and her ultimate conclusion that Michael's seizures and retardation were attributable to his genetic disease. Pet. App. 115a, 127a. In *Plavin*, the court also affirmed the special master's decision to reopen entitlement proceedings, concluding that her discretion was not abused. *Id.* at 100a-105a. Similarly, it found the special master's determination that TS was a permissible alternative cause under the Vaccine Act to be in accordance with the statute. *Id.* at 98a, 141a. However, the court remanded the latter case for the limited purpose of determining whether the Secretary had proven that TS was the actual cause of Rachel's seizures and mental retardation based upon the specific symptoms she experienced, and the course of her disease. *Id.* at 109a. After considering additional evidence on remand, the special master again concluded that the child's seizures and retardation were caused by her TS. *Id.* at 136a. The Court of Federal Claims affirmed the special master's remand decision and dismissed the case. *Id.* at 142a.[2]

5. The Court of Appeals for the Federal Circuit affirmed the dismissal of the petitions. Pet. App. 143a, 151a. The court determined that the special master's finding that TS was the actual cause of petitioners' seizures and retardation was based on a "logical and legally probable" sequence of cause and effect. *Id.* at 149a. The court also found that it was "not an abuse of discretion" for the special master to "consider new

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[2] Because the sole argument petitioners raise in their petition for certiorari is whether the special master erroneously decided to reopen entitlement proceedings in the first instance, neither the special master's remand order nor any of the findings below regarding the nature and course of petitioners' genetic disease are before this Court.

pertinent medical evidence that was not available at the time of the original petition." *Ibid.* A combined petition for rehearing and suggestion for rehearing en banc was denied. *Id.* at 152a-153a.

ARGUMENT

In their petition for a writ of certiorari, petitioners have abandoned most of the arguments pursued below. Specifically, they do not renew either their objections to the special master's findings regarding the nature of the genetic disease and the unfortunate and devastating symptoms caused by that disease, or their objections to the legal sufficiency of TS as a permissible alternative cause under the Vaccine Act. Those issues are therefore not before the Court.

The sole claim on certiorari is that it was error for the special master to reconsider her initial decision on entitlement to compensation while the case was still pending before her and prior to the entry of final judgment. In rejecting petitioners' claims, the Court of Federal Claims and the Federal Circuit correctly concluded that the special master acted well within her statutory discretion in granting the Secretary's motion for reconsideration based on new and dispositive medical evidence. The decisions below comport both with the text and purposes of the Vaccine Act, and with broader legal doctrine. They do not create any conflict, either among federal courts of appeals or within the Federal Circuit. Further review is not warranted.

1. The Vaccine Act affords a special master "wide discretion in conducting the proceedings in a case." *Burns* v. *HHS*, 3 F.3d 415, 417 (Fed. Cir. 1993); accord *Murphy* v. *HHS*, 23 Cl. Ct. 726, 730 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied, 506 U.S. 974 (1992). Congress charged the special masters to be "vigorous

and diligent in investigating" Vaccine Program claims, and the legislative history provides that their fact-finding mission should be carried out in an "inquisitorial" manner. H.R. Rep. No. 908, *supra*, at 17; H.R. Rep. No. 247, 101st Cong., 1st Sess. 764 (1989). Thus a special master "may require the testimony of any person and the production of any documents as may be reasonable and necessary." 42 U.S.C. 300aa-12(d)(3)(B)(iii); accord 42 U.S.C. 300aa-12(d)(3)(B)(iv) (special master shall consider "all * * * relevant written information"). Moreover, with respect to receiving evidence, a special master "will not be bound by common law or statutory rules of evidence." *Hines* v. *HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The Vaccine Rules promulgated by the Court of Federal Claims pursuant to Congress's authorization instruct a special master to "consider all relevant reliable evidence, governed by principles of fundamental fairness to both parties." Fed. Cl. Ct. R. 8(b), App. J. Additionally, although the Office of Special Masters initially issued only recommendations to the Court of Federal Claims, Congress subsequently accorded special masters final decision-making authority. Congress intended for "appeal of the special master's decision," only "under very limited circumstances," H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 253 (1989). Challenges to discretionary rulings—the essence of petitioners' claims on petition for a writ of certiorari—are therefore restricted by statute to review for abuse of discretion. 42 U.S.C. 300aa-12(e)(2)(B) (findings of fact or conclusion of law may be set aside if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

Consistent both with the wide discretion afforded under the Vaccine Act and with well-accepted judicial

doctrine, a Vaccine Act special master—like *any* court or statutory fact-finder—"may change any interlocutory decision up until the entry of final judgment." *McGowan* v. *HHS*, 31 Fed. Cl. 734, 737 (1994); *Horner* v. *HHS*, 35 Fed. Cl. 23, 27 (1996) (remanding to the special master with directions to reopen the proof to consider the admission of a newly-offered vaccination record, stating that "fundamental fairness requires a search for the truth," which search is furthered by examining "newly found and offered evidence"); *Shaw* v. *HHS*, 18 Cl. Ct. 646, 652 (1989) ("Until entry of judgment, the record of proceedings is not closed and this court retains an obligation to consider all scientific, medical, and legal matters brought to its attention by either party."). Far from being a "jurisprudential aberration," Pet. 13, this practice mirrors the discretion to reconsider interlocutory rulings approved both by this Court and by the Federal Circuit in a variety of contexts.[3] Thus the special master's decision to reconsider her earlier entitlement rulings was not, as petitioners

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[3] See, *e.g.*, *United States* v. *Pierce Auto Freight Lines*, 327 U.S. 515, 535 (1946) ("[I]t has been held consistently that rehearings before administrative bodies are addressed to their own discretion * * *. Only a showing of the clearest abuse of discretion could sustain an exception to that rule."); *Jamesbury Corp.* v. *Litton Indus. Prods., Inc.*, 839 F.2d 1544, 1550-1551 (Fed. Cir.) (where "case was before the district court for 9 years, and much is known now that was not known at the time of the original motion," the court did not abuse its discretion in reconsidering its decision), cert. denied, 488 U.S. 828 (1988), overruled on other grounds, *A.C. Aukerman Co.* v. *R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992); *Genentech, Inc.* v. *United States Int'l Trade Comm'n*, 122 F.3d 1409, 1422 n.13 (Fed. Cir. 1997) ("Genentech now asserts that the prior ruling was 'law of the case.' We disagree. The ALJ has the power to reconsider a prior decision in the same proceeding.").

contend, barred by the "law of the case" doctrine, for it is axiomatic that "[i]nterlocutory orders * * * do not constitute the law of the case." *Pérez-Ruiz* v. *Crespo-Guillén*, 25 F.3d 40, 42 (1st Cir. 1994); see *In re PCH Assocs.*, 949 F.2d 585, 592 (2d Cir. 1991) (law of the case is a "discretionary rule of practice and generally does not limit a court's power to reconsider an issue"); see generally 18 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* 4478 (Supp. 1999) ("Although courts are often eager to avoid reconsideration of questions once decided in the same proceeding, it is clear that all federal courts retain power to reconsider if they wish."); 18 James W. Moore et al., *Moore's Federal Practice and Procedure* 134.22(1)(a) (3d ed. 2000) ("The law of the case doctrine does not * * * limit the court's power to reconsider or change its decision.").

Against this backdrop, it is clear that the issue raised by the petitioners does not warrant this Court's review. The interlocutory entitlement rulings in these cases were not "final," Pet. 6, ¶ 9; no judgment had been entered, nor had there been any intervening appeal to the Court of Federal Claims that might otherwise have deprived the special master of the authority to consider the Secretary's motions.[4] The impetus for the Secre-

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[4] The fact that the Office of Special Masters routinely bifurcates proceedings—addressing entitlement first and then, if necessary, going on to determine damages—does not make a special master's interlocutory entitlement decision "final." Indeed, as petitioners note, the practice of bifurcation avoids "needless or duplicative expenditures of money," Pet. 10, as well as unnecessary expenditure of judicial resources. That procedural practice does not change the nature of the special master's authority, nor does it give petitioners any vested rights. See generally *United States* v. *Torbert*, 496 F.2d 154, 157 (9th Cir.) (a court's "General Order is a

tary's motion was a new study, published by the Mayo Clinic in January, 1995. Pet. App. 101a. The Secretary immediately brought this material to the special master's attention, and moved for reconsideration in a timely manner: within ten months of the initial entitlement ruling in *Hanlon*, and within three months of the initial ruling in *Plavin*. After the motions were granted, significant additional medical evidence was submitted to the special master by both parties.

Not only was the special master well within her discretion to examine the most current medical information and apply it in pending cases, her efforts were fully in keeping with her statutory charge to consider "all * * * relevant written information." 42 U.S.C. 300aa-12(d)(3)(B)(iv). That the proffered evidence was relevant is clear: compensation in Vaccine Act cases is statutorily barred where a claimant's injury or condition is due to a factor or cause unrelated to immunization. 42 U.S.C. 300aa-13(a)(1)(B). Indeed, in general, the *refusal* to consider potentially dispositive new evidence in Vaccine Act cases has been repeatedly found to be an abuse of discretion. See *Vant Erve* v. *HHS*, 39 Fed. Cl. 607 (1997) (despite three-year time lapse since entitlement determination, special master's refusal to consider diagnosis of alternative etiology constituted abuse of discretion), aff'd, No. 99-5093 (Fed. Cir. Apr. 18, 2000); *Kaminski* v. *HHS*, 39 Fed. Cl. 253 (1997) (special master abused her discretion in refusing to reconsider entitlement decision based on additional

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housekeeping rule for the internal operation of the district court * * *. [I]t does not give appellant a vested right to any particular procedure."), cert. denied, 419 U.S. 857 (1974); accord *Sinito* v. *United States*, 750 F.2d 512, 515 (6th Cir. 1984) ("internal housekeeping rules * * * promote the efficient operation of the district courts; they are not meant to confer rights on litigants").

fact testimony); *Horner*, 35 Fed. Cl. at 26 (special master's refusal to consider new evidence an abuse of discretion); *Davis* v. *HHS*, 19 Cl. Ct. 134, 143 (1989) (remanding case and ordering special master to consider evidence of "alternative etiology"); *Koston* v. *HHS*, 23 Cl. Ct. 597, 603 (1991) (special master's refusal to consider request to amend pleadings in light of new evidence an abuse of discretion), aff'd on other grounds, 974 F.2d 157 (Fed. Cir. 1992).

3. Petitioners erroneously claim that the Federal Circuit's decision in *Suel* v. *HHS*, decided by the same panel that ruled on the *Hanlon* and *Plavin* cases, is relevant to the instant petition.[5] Petitioners mischaracterize both the issue in *Suel* and its import. In *Suel*, the special master initially issued a final decision denying entitlement to compensation. *Suel* v. *HHS*, No. 90-935V, 1993 WL 241430 (Fed. Cl. June 18, 1993). On petitioners' appeal, the Court of Federal Claims reversed that decision and remanded the case for a determination of the amount of compensation. Subsequent to that remand, the Secretary sought to reopen for consideration of the evidence from the omnibus hearing.

Two critical factors arising from the cases' procedural posture distinguish *Suel* from *Hanlon* and *Plavin*. First, unlike the instant cases, *Suel* had already been appealed to the Court of Federal Claims on the question of entitlement to compensation, and was pending on remand for a determination of the amount of

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[5] Subsequent to filing their petition for a writ of certiorari, petitioners filed a motion in this Court to "delay consideration" of their petition "in anticipation of a related case," maintaining that the government was likely to petition for a writ of certiorari in *Suel*. We do not intend to file such a petition. That case turned on the peculiar details of its procedural posture, and we do not deem the issues worthy of review beyond panel rehearing.

compensation, when the Secretary sought to introduce the same new evidence that the special master considered in the *Hanlon* and *Plavin* cases. *Suel* v. *HHS*, 31 Fed. Cl. 1 (1993), aff'd, 192 F.3d 981 (Fed. Cir. 1999). Indeed, the remand decision was issued almost two years prior to the date that new evidence became available.

Second, unlike the present cases, *Suel* involved an appeal of the special master's *denial* of the Secretary's motion to consider new evidence. The decision to deny the motion based on the particular procedural posture of *Suel*, like the decision to grant the Secretary's motion given the distinct procedural posture of *Hanlon* and *Plavin*, was subject to review under a highly deferential standard—abuse of discretion.

Although the Secretary urged both to the Court of Federal Claims and the court of appeals that the special master erred in *refusing* to consider the evidence garnered at the omnibus hearing in *Suel*, the Federal Circuit disagreed. The court held that the Court of Federal Claims' 1993 "reversal of the initial entitlement claim was a final judgment," *Suel* v. *HHS*, 192 F.3d at 984, and that therefore, the special master "lacked the authority to reconsider the issue of entitlement unless a motion for reconsideration was granted by the Court of Federal Claims." *Ibid.* The court further determined that the evidence compelling the special master to reopen *Hanlon* and *Plavin* "was not correctly in the record [in *Suel*] absent a prior negation of the 1993 entitlement determination." *Id.* at 986-987. The Federal Circuit therefore affirmed the underlying refusal to consider that evidence and in turn the award of compensation, and denied further review.

In the present cases, of course, there was no intermediate decision of the Court of Federal Claims; the

special master retained authority to reconsider any previous orders so long as the cases remained pending before her, and simply exercised her discretion to do so. There is nothing inconsistent in the fact that the Federal Circuit affirmed both the denial of compensation in *Hanlon* and *Plavin*, and the award of compensation in *Suel* based upon the cases' distinct procedural postures and deferential standard of review. There was nothing done below in *Hanlon* or *Plavin* that might reasonably be characterized as an abuse of discretion, nor are there any other reasons warranting this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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